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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/765,547 | 01/26/2004 | Seung-Hak Choi | YPL-0077 | 1634 |

7590 04/17/2007
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| EXAMINER |
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ZHOU, SHUBO

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| ART UNIT | PAPER NUMBER |
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1631

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 04/17/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/765,547 | Applicant(s) CHOI ET AL. | |
| | Examiner Shubo (Joe) Zhou | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 9-11 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendments

1. Applicants' amendments and request for reconsideration filed 1/22/07 are acknowledged, and the amendments entered. New claims 12-14 have been added.

Claims 1-14 are currently pending and under consideration.

Claim Rejections-35 USC § 101/112, second paragraph

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

This rejection is newly applied.

Claims 1-8 are drawn to a system. However, it is not clear as to which category of the statutory subject matter the claimed system belongs. The system includes "a server" that includes databases, which server appears to be part of a machine, and "a client receiving results of a biochip test, accessing ..., performing ..., and storing ...," which appears to be a step of a process.

MPEP 2173.05(p):

II. PRODUCT AND PROCESS IN THE SAME CLAIM

A single claim which claims both an apparatus and the method steps of using the apparatus is indefinite under 35 U.S.C. 112, second paragraph. ** > IPXL Holdings v. Amazon.com, Inc., 430 F.2d 1377, 1384, 77 USPQ2d 1140, 1145 (Fed. Cir. 2005); < Ex parte Lyell, 17 USPQ2d 1548 (Bd. Pat. App. & Inter. 1990) * > (< claim directed to an automatic transmission workstand and the method * of using it * held ** ambiguous and properly rejected under 35 U.S.C. 112, second paragraph >) < .*

Such claims ** > may <* also be rejected under 35 U.S.C. 101 based on the theory that the claim is directed to neither a “process” nor a “machine,” but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. 101 which is drafted so as to set forth the statutory classes of invention in the alternative only. *Id.* at 1551.

Thus claims 1-8 are directed to nonstatutory subject matter because they are directed to neither a “process” nor a “machine,” but rather something that embraces or overlaps two different statutory classes.

5. Claims 1-8 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are rejected for the reasons as set forth above in the MPEP cited above.

This rejection is also newly applied.

Claim Rejections-35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Osborne et al. (IDS document: Artificial Intelligence System for Genetic Analysis, WO 01/16860 A2, March 8, 2001).

The claims are drawn to a server-client network for genotyping analysis on a target sample. The network comprises a server including databases required for the genotyping analysis and providing the databases to a client, and the client receiving the results of a biochip test on the target sample with reference to the databases provided from the server.

With regard to at least independent claims 1 and 12, Osborne et al. disclose a network system and a method for genetic analysis. The network system comprises a server that includes multiple databases required for the genetic analysis, which are provided to client that receives the results of a microarray analysis and performs the genetic analysis. See at least Fig. 1. and pages 4-5. The genetic analyses include analysis of genomic mutations (see page 12, lines 30-31), which is interpreted as a type of genotyping. Osborne et al. disclose that the system comprises central data processing facilities and user facilities and that “each user facility may include an optical scanning system to collect hybridization signals from a nucleic acid array, an image processing system to convert the optical data into a set of hybridization parameters, a connection to a data network, and a user interface to display, manipulate, search, and analyzed hybridization information.” See page 5. The system comprises various types of users at different tiers including remote users/local users, web users/internet users, diagnostic users including diagnostic master users, and browser users (see pages 10-12), any of which is interpreted as being part of the client as recited in the instant claims. Since the user facilities (interpreted as client) and the central data processing facilities (interpreted as server) comprising the databases are linked by encrypted network connections (see page 5), it is interpreted that the databases in the server are provided to the client. Furthermore, Osborne et al. disclose that “users perform statistical tests on cataloged hybridization profiles stored in the central data processing facility” and “a web user or browser

user may search the artificial intelligence system and view statistical summaries of the databases” and “use the database to search, correlate, manipulate, and display existing data.” See page 15.

With regard to claims 2 and 13, the databases in the server disclosed by Osborne include database for chip ID and pattern/layout, analysis algorithm and a quality control database. See at least Fig. 1 and pages 5-7, 10, 12-14, and 27. See also pages 19-22 for rules/algorithm for analysis in the system.

With regard to claims 3-4, the server of the system by Osborne et al. comprises database that is built up from statistical data for the results of test on a number of patients and references samples using microarrays. Osborne et al. disclose that the database server stores hybridization profiles, patient profiles, reference information, clinical information associated with hybridization profiles, and statistical summaries. See page 5. Osborne et al. further disclose that “hybridization profiles collected by remote and/or local facilities include clinical observations or other information associated with each profile, and the profile with associated observations is added to the central database.” See page 6. Osborne et al. also state that “the databases of the instant invention continually mature and develop into more and more complex systems as information from public and private sources continues to be added to the existing database.” See pages 13 and 15. Thus, the databases are being built up while the users use the system.

With regard to claim 5, in the system disclosed by Osborne et al., the users/clients comprise optical scanning system and identifier recognizer. See at least Fig. 1 and pages 11 and 16.

With regard to claims 6-8 and 14, which include limitations that the client comprises an engine for performing a series of logical functions, in the system disclosed by Osborne et al., the client comprises an engine or means for performing a function of detecting the identifier of the biochip (see Fig. 1 and the “application ID on at least page 16, array ID and array location ID on

at least pages 26-27, and sample ID, patient ID, etc. on pages 28-29). Client can select and download data/database based on application ID, etc., and perform genotyping analysis. See the diagnostic architecture listed on pages 16-18. Furthermore, with regard to claim 8, the method of Osborne et al. allows client to perform the genetic analysis including reading results via scanning system, (see pages 16-18), linking results with spot position information of the chip, etc. (see pages 13-14, where the database queries include chip ID genetic pattern, pattern match, result output, etc. and page 15). Users can perform functions such as correlating they hybridization signals of one or more probes and creating test hypothesis relating to a particular pathological or physiological condition, using the server databases to search, correlate, manipulate and display existing data, etc. See page 15.

With regard to claims 9-11, which are drawn to computer readable medium comprising computer executable instructions for executing the method steps and functions performed by the system above, given that the system for performing the functions and method steps as set forth above is a web-based computer systems including server and client, it would be readily recognized by one skilled in the art that the system inherently comprises computer readable medium containing computer executable instructions for performing the functions. This rejection is reiterated from the previous Office action mailed 9/21/06 with regard to claims 1-11 and newly added with regard to new claims 12-14.

Applicant's arguments filed 1/22/07 have been fully considered but they are not found persuasive. The arguments are on the ground that Osborne et al. do not teach "storing results of the genotyping analysis in the client of amended claims 1 and 9." See page 10 of 13 of the response. This is not found persuasive because firstly, the claims do not explicitly define "results" as all or part of the results of the genetic analysis, and secondly, there is no time requirements as to when the results are stored in the client. As applicant admits on page 10 of 13 of the response, Osborne et al. disclose that some of the results of the genetic analysis are sent

Art Unit: 1631

back to the client. It would thus be readily apparent to one skilled in the art that the results are stored there with the client. Applicant further argues that Osborne et al. do not teach “receiving databases” and “the received databases comprising an analysis algorithm databases storing algorithms.” See page 11 of 13 of the response. This is also not found persuasive. Osborne et al. state on page 12:

There are two categories of diagnostic users, such as "diagnostic master users" and "diagnostic users". Accounts for diagnostic master users are authorized and correspond to the user sites where the systems are deployed. These diagnostic master users are allowed to authorize accounts for diagnostic users. For clinical applications, diagnostic users correspond to the individuals that have been tested. For research and development applications, diagnostic master users can designate either individual chip test results or groups of chips as a single diagnostic user, wherein this option lies with the diagnostic master users in order to meet their testing and analysis needs. Diagnosis processing is a key part of the artificial intelligence system. The diagnosis processing for clinical applications may be different from that of research and development applications. Diagnosis processing for clinical applications implements a rules based analysis application which utilizes a database set of rules and results. Diagnosis processing thereby determines which conditions apply to the various combinations of gene expression levels and personal medical history.

This clearly indicates that for a diagnostic user, i.e. client, to perform the diagnosis processing, the user first receives the systems because they “are deployed.” The system includes databases of rules, etc., which are interpreted as algorithms.

Claim Objections

8. Claims 9-11 are objected to because of the following reasons including informalities:

It appears that the mark “;” in line 3 of claim 9 should be “:”.

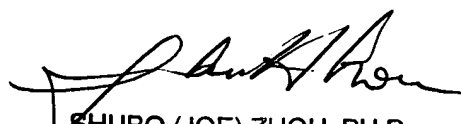
Appropriate correction is required.

Conclusion

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, Ph.D., whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D., can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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PATENT EXAMINER